

## **REMARKS/ARGUMENTS**

### ***Status of the claims***

Claim 17-20 and 22 are pending in the application. Claim 17 is under examination.

With entry of the instant amendment, claim 17 and withdrawn claims 18 and 22 have been amended to recite Factor VIII:C that is free of measurable platelet agglutinating vWF activity as determined by measuring vWF:Risto-CoF activity. This amendment adds no new matter. Support can be found, *e.g.*, at page 19, lines 4-10 and in Table 1 (page 20) and Table 4 (page 25).

Applicants have also corrected a typographical error in withdrawn claim 22 that was inadvertently introduced in a previous amendment. This corrects “vWF” to read “vWD” at line 1. The “vWF” term appears to have been inadvertently introduced at line 1 in the amendment filed May 7, 2008, although claim 1 had not been amended to replace “vWD” with “vWF”.

Applicants thank the Examiner for the interview on May 28, 2009 and the subsequent follow up phone call on June 2, 2009. The rejections under 35 U.S.C. § 112, first paragraph and second paragraph regarding the term “substantially free” and potential claim amendments were discussed during the May 28, 2009 interview.

### ***Rejection under 35 U.S.C. § 112, first paragraph***

Claim 17 is rejected as allegedly lacking proper written description support. The Examiner contends that the specification does not describe “substantially free of platelet agglutinating activity”. Although Applicants disagree, in the interests of expediting prosecution, claim 17 has been amended as explained above. The specification provides guidance for determining a Factor VIII:C free of platelet agglutinating vWF activity as measured by assessing vWF-Risto-CoF activity. For example, the last sentence of page 7 bridging to page 8 of the specification teaches that free Factor VIII:C and low molecular weight multimers and degradation products are eluted from a cation exchanger at a salt concentration of between  $\geq 250\text{mM}$  and  $\leq 300\text{mM}$ . The examples, *e.g.*, Table 1 and Table 4, teach that fractions that were

eluted from the cation exchangers with 0.3 M NaCl (Table 1) and 0.25 M NaCl (Table 4) did not exhibit measurable vWF:Risto-CoF activity. As previously explained, the vWF:Risto-CoF activity has long been used by those in the art to measure platelet agglutinating vWF activity. In view of the foregoing, the specification adequately conveys to one of skill in the art that Applicants were in possession of the claimed invention. It is therefore requested that this rejection be withdrawn.

***Rejection under 35 U.S.C. § 112, second paragraph***

Claims 17 is rejected as allegedly indefinite over the recitation of "substantially free". Although Applicants disagree for reasons previously of record, in the interests of expediting prosecution, claim 17 has been amended as described above. Applicants therefore respectfully request withdrawal of the rejection.

***Rejoinder***

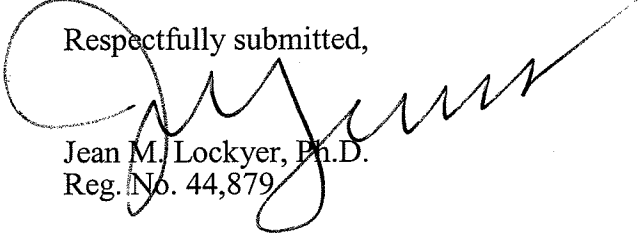
Upon determination that claim 17 is allowable, Applicants respectfully request rejoinder of claims 18-20 and 22, as the amended claims would have all of the limitations of an allowable claim 17.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

  
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